

#### **NAHLN Update**



#### **June 2011**

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#### **Presentation Overview**



History and Background

**Current Capabilities** 

**Application of Capabilities** 

2011 Activities to Enhance Capabilities

Conclusions

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#### The National Animal Health Laboratory Network

- Formed in 2002
- Is a group of State funded veterinary diagnostic labs that deal with diseases of animals including endemic, exotic, zoonotic, and emerging diseases
- Is a partnership between:
  - USDA (APHIS and NIFA)
  - AAVLD
  - NAHLN Laboratories

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#### The Purposes of NAHLN

- Early detection
  - Targeted surveillance based on population density & risk
- Rapid response
  - Surge capacity to test outbreak samples
- Appropriate recovery
  - Large numbers of samples tested to show freedom

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#### Founding Principles and Features of NAHLN

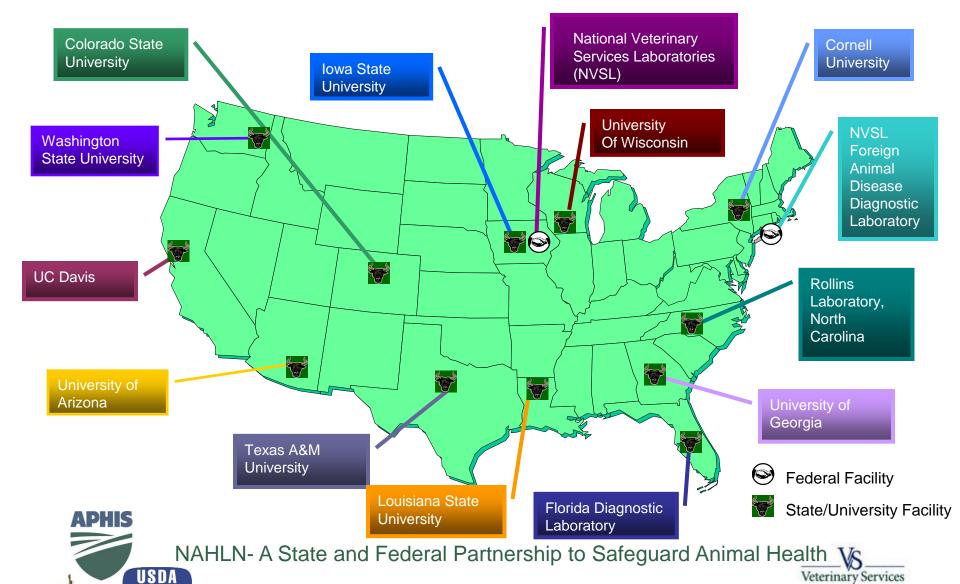
- Standardized, rapid diagnostic techniques
- Secure electronic communications and reporting system
- Trained personnel, modern equipment
- Quality standards, proficiency testing
- Adequate facility biosafety/biosecurity levels
- Scenario testing
- Laboratory review and approval process

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#### The original 12 NAHLN laboratories





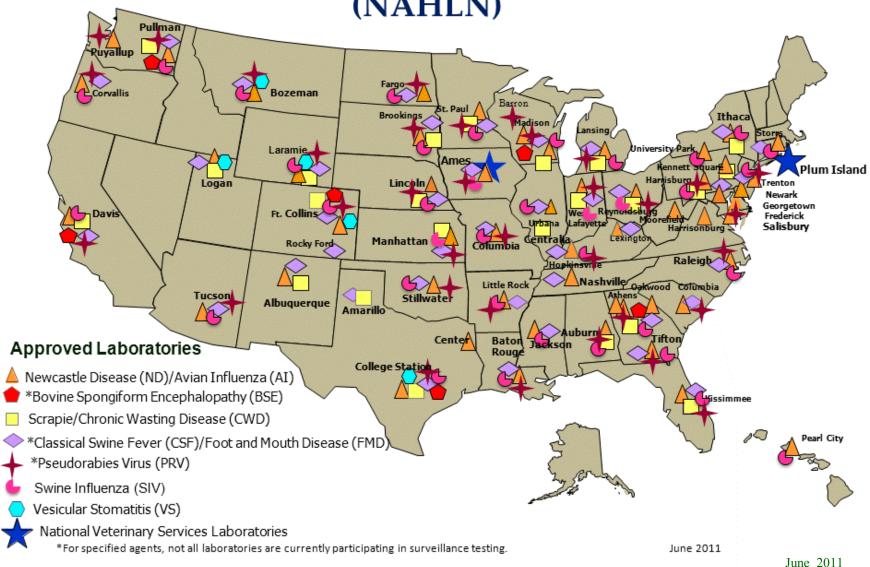
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The SOUND-ME



## National Animal Health Laboratory Network (NAHLN)





#### Designation of Laboratories in the NAHLN

- Core Member laboratory labs that are receiving significant infrastructure support and are conducting fee for service testing from USDA. This group currently includes the original 12 laboratories.
- Member laboratory labs that are receiving limited annual support from USDA for specific purposes and also perform fee for service testing.
- Contract Member laboratory labs that are performing fee for service testing for control of specific animal diseases ONLY.
- Adjunct Member laboratory labs that wish to be members of the NAHLN but whose primary mission is not domestic animal disease diagnostic work within the United States.

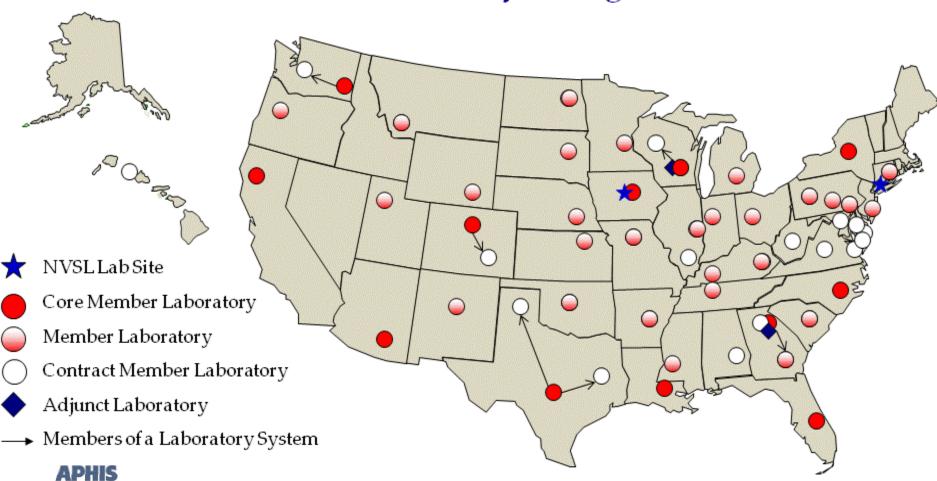
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#### NAHLN Laboratory Designations



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Laboratory
Designation

#### NAHLN Laboratory Requirements



#### Adjunct Member Laboratory

- 1. QA System implemented
- 2. Quality Manager
- 3. Trained staff in molecular diagnostic testing

#### **Contract Member Laboratory**

- 1. QA System implemented
- 2. Quality Manager
- 3. Trained staff in molecular diagnostic testing
- 4. Participation in various surveillance activities
- 5. Functional Laboratory Information Management System (LIMS)
- 6. Test data reported within time frames indicated in SOPs

#### Member Laboratory

- Fully or provisionally accredited by AAVLD or by an accrediting body according to the OIE/ISO 17025 standard to cover the scope of NAHLN testing
- 2. Active participation in electronic messaging of surveillance test results
- 3. Trained staff in molecular diagnostic testing
- 4. Participation in various surveillance activities
- 5. Test data reported within time frames indicated in SOPs

#### Core Member Laboratory

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- 1. Fully accredited by AAVLD or by an accrediting body to the OIE/ISO 17025 standard to cover the scope of NAHLN testing
- 2. Provides and maintains BSL3 laboratory space with sample handling, processing, and testing capacity
- 3. Shall agree to send staff out to other labs or the field for emergency operations
- 4. Shall provide train the trainer expertise, as requested
- 5. Competence, capability, and capacity for high-throughput testing
- 6. Active participation in electronic messaging of surveillance test results
- 7. Test data reported within time frames indicated in SOPs
- 8. Agrees to assist other laboratories to develop and implement IT capabilities
- 9. Shall accept samples from other states impacted by a disease outbreak
- 10. Provides funding associated with maintaining equipment and laboratory space used for NAHLN purposes

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# **Current Capabilities**

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#### Standardized Rapid Diagnostic Techniques

- NAHLN Methods Technical Working Group
  - Purpose: to provide input on various aspects of methods validation and approval
    - Review of available methods and associated gaps
    - Identification of potential new technologies
    - Validation and methods comparison criteria and approval processes
    - Dossier review and assay approval process
    - Continual performance assessment of assays
- Current standardized methods:
  - AI, BSE, CSF, CWD, END, FMD, PRV, SIV, Scrapie, VSV

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## Secure Communications and Reporting System NAHLN IT System

- Established a system with data and messaging standards to ensure accurate and consistent diagnostic information is quickly and securely transmitted.
  - NAHLN IT Committee
- Laboratories messaging into NAHLN IT system
  - 13 CSF
  - 12 AI

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## Trained Personnel and Modern Equipment Train the Trainer Program

- Established 2005 in response to need to increase number of people trained and proficiency tested to address animal health emergencies
- Incremental growth of approved laboratories and analysts

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	Approved Laboratories		Approved Analysts	
Disease/Agent	FY2004	FY2010	FY2004	FY2010
AI	15	54	28	218
CSF	12	39	24	169
END	15	52	28	207
FMD	12	40	24	174

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## Quality Standards and Proficiency Testing Proficiency Testing Program

- NVSL National reference lab
  - Provides proficiency test panels and reference materials
- Requirement must successfully complete proficiency test process to participate in NAHLN surveillance activities
  - Competency assessment
  - Frequency
    - 6 months to 1 year
- Diseases/agents
  - AI, ASF, BSE, CSF, CWD, END, FMD, PRV, rinderpest, scrapie, SIV, VSV

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## Quality Standards and Proficiency Testing Quality Management System Training

- AAVLD, ISO 17025/ OIE standard
  - Document control, records, internal auditing, management review, corrective actions, root cause analysis
- Interactive learning environment
  - Wet lab application of skills
- 2010 training 87 participants representing 52 labs
  - 40 NAHLN laboratories
  - 8 prospective laboratories
  - 3 Federal and one international lab
- Summary report and recommendations





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#### **Scenario Testing**

- 2008 Highly Pathogenic Avian Influenza
  - 38 Regional presentations in 2008
  - 700 Participants
    - Animal Health
    - Public Health
- 2010 Foot and Mouth Disease
  - Inspired by the 2007 HPAI Exercise Series
  - 5 part series

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- VS Policy-level workshop
- Kansas State table top exercise
- 15 follow-up exercises
- NVSL table top exercises
- Follow-up policy exercise



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#### Laboratory review and approval process

- Developed in conjunction with AAVLD Accreditation Committee
  - Consistent with ISO 17025/ OIE standards
  - Site visits
  - Audit report and response
  - Piloted 2008, implemented 2009
- Evaluation of processes and Annual Report
  - Input from audited labs and stakeholders
  - Establish annual goals and recommendations
- Development of associated audit documents
  - NAHLN Audit SOP
  - Guidance documents

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# Application of Capabilities

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#### **Surveillance Programs**

- Surveillance plan, procedure manual and communication guidance
- Diseases/agents
  - AI/NDPRV
  - BSE– CWD & Scrapie
  - CSF SIV
  - VSV
- Benefits

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- Early detection
- Increased technical proficiency
- Improved communication
- Improved preparedness

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#### **Classical Swine Fever**

- 1<sup>st</sup> Plan developed by National Surveillance Unit with stakeholder input
  - Target clinical signs, feral swine, slaughter condemned
  - All high risk states involved
- Implemented in January 2006
- Personnel from 40 laboratories trained and PT'd
- >6000 samples tested / year
- Data submission
  - Web based and electronic messaging



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#### **Swine Influenza Virus**

- Implemented in May 2009
- Personnel from 36 laboratories trained and PT'd
  - Personnel must have successfully completed AI PT
- Approved screening assays
  - Matrix PCR
  - N1 PCR

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- Virus Isolation
- Sequencing
- >1200 samples tested / year
- Target diagnostic samples from swine with clinical signs





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#### **Avian Influenza and Newcastle Disease Virus**

- Personnel from 53 laboratories trained and PT'd
- Conducting surveillance using rRT-PCR
  - Veterinary Services
  - Wildlife Services
- >40,000 samples tested / year for Al surveillance in wildbirds



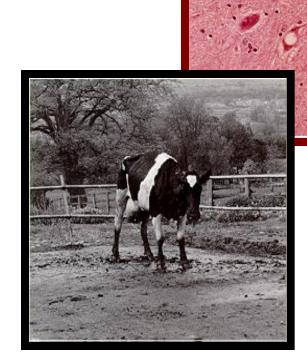
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#### **Bovine Spongiform Encephalopathy**

- Personnel from 6 laboratories trained and PT'd
- Enhanced surveillance
  - >959,800 samples tested since
     June 2004
- Maintenance surveillance
  - September 2006
  - > 40,000 samples/year



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#### **Chronic Wasting Disease and Scrapie**

- Personnel from 23
   laboratories trained and PT'd
- >19,000 CWD samples tested/year
- >45,000 Scrapie samples tested/year



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#### **Pseudorabies Virus**

- Personnel from 34 laboratories trained and PT'd
- Pilot surveillance began in 2009
  - 10 NAHLN Laboratories participated
- 2010 PRV Surveillance
  - 16 NAHLN Laboratories participating
- >18,000 samples tested / year



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#### **Vesicular Stomatitis Virus**

- Personnel from 5 laboratories trained and PT'd
- Activated following confirmation of an outbreak
- Equids only

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Serology – CF test



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#### **Foot and Mouth Disease**

- Personnel from 40 laboratories trained and PT'd
- Assay validated
  - Dossier review in 2007
  - Negative cohort 2010-2011
- Use of assay in an outbreak situation



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## Testing Samples from Foreign Animal Disease Investigations

- Revisions to VS Memo 580.4
  - Procedures for a suspected FAD or EDI
  - Samples can be split and sent to NVSL and approved NAHLN labs
  - Confirmatory testing at NVSL
- Decrease time for screening test results
- Tools for implementation
  - 580.4 Flow Charts and Ready Reference Guide

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# 2011 Activities to Enhance Capabilities

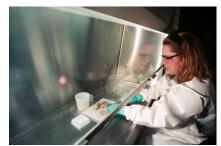
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#### Standardized, Rapid Diagnostic Techniques Diagnostic Development - FADDL and NAHLN

- NAHLN Methods Technical Working Group processes
- Deployment of FMD Serology to NAHLN labs
- Optimization of RNA extraction for early detection of FMD virus in milk from experimentally infected cows
- Enhancements to Molecular Diagnostics for FMD and CSF
- Validation of real time PCRs for Bovine Contagious Pleuropneumonia and Lumpy Skin Disease
  - Continuation of Negative Cohort studies in NAHLN labs



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## Secure Communication and Reporting System NAHLN IT Priority Activities

- Training for Member labs to begin messaging
- Development of order messaging
- Messaging for and/or integration of existing databases:
  - SIV
  - Scrapie/CWD
  - PRV
  - FMD
- Messaging for additional diagnostic assays technologies
  - ELISA
  - IHC
  - VI and sequencing

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## Secure Communication and Reporting System Laboratory Capacity Estimation Program

- Collaboration between NAHLN/FAZD/AAVLD
- Software tool for evaluating/monitoring NAHLN capacity
  - Daily testing and surge
- Project Objectives:
  - Improve knowledge in individual and overall NAHLN diagnostic testing
  - Prioritization of resources
  - Serve as critical tool for managing a large number of diagnostic tests simultaneously

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## Secure Communications and Reporting System NAHLN Portal

- Development in cooperation with KSU and UMN
- Modules
  - Secure mechanism to electronically comment on and release SOPs.
  - Laboratory directory including information on physical space, personnel and equipment.
  - Mechanism to monitor assay performance
  - Mechanism to submit and receive PT results
  - Mechanism to train others in the validation process.
  - Work Group and collaboration space to post documents and schedule meetings and calls.
  - Mechanism to schedule meetings and training.
- User acceptance testing by NAHLN

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## Quality Standards and Proficiency Testing NAHLN Outreach and Training

- Expansion of quality management training
  - Distance and on-line delivery
  - Involvement of other networks
  - Additional training sessions
  - Potential international delivery and participants

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## Scenario Testing NAHLN Program Support for Laboratories

- Finalize NAHLN operational plan
- Disease outbreak guidelines
  - Use of BSL 2 vs. BSL 3 space
  - Compliance with select agent rule
  - Use of proficiency tested personnel
  - Timelines for reagents and support by other labs
  - Process for financial reimbursement
- NAHLN laboratory triage template

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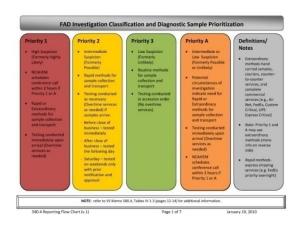
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## **Scenario Testing** *VS Memo 580.4 Training*

- Work with VS NCAHEM and PDS to improve understanding, use and implementation of VS Memo 580.4
  - APHIS and State field personnel
  - Lab personnel



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#### **Conclusions**

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#### Successes of the NAHLN

- Strategically combines the infrastructure and expertise in the state veterinary diagnostic laboratories and the National Veterinary Services Laboratories.
- Established the animal health laboratory backbone of the United States emergency response and recovery program.
- Implemented national, standardized surveillance for high priority diseases.

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#### **Conclusions**

- Increased levels of coordination and collaboration have increased capabilities
- Tremendous progress in the ability to respond
- Much remains to be accomplished
- Partnerships are key to the success of NAHLN!

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#### **NAHLN Information**

- Brochure and Information Cards
- Posters
- Website: <a href="http://www.aphis.usda.gov/animal\_health/nahln">http://www.aphis.usda.gov/animal\_health/nahln</a>
- Contact information:

E-mail <a href="mailto:nahln@aphis.usda.gov">nahln@aphis.usda.gov</a> or phone 515-337-7731

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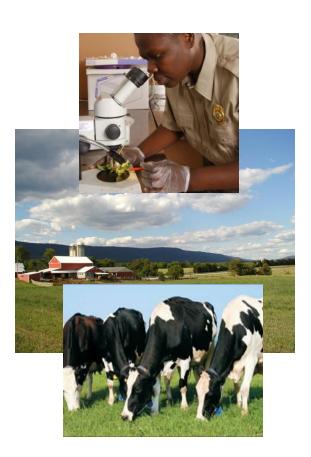
#### **Questions?**



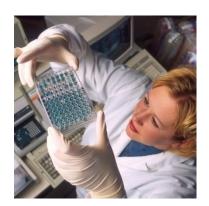


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